

*Amendment and Response to Office Action*  
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### REMARKS

The present application is directed to a method and kit for detecting animal byproducts in samples. The method and kit are particularly useful in the detection of animal byproducts in feed, such as animal byproducts rendered in bone meal. Detection of animal byproducts in feed is useful for reducing transmission of pathogens such as those causing mad cow disease.

Following entry of this amendment, Claims 1-7, 10-11, 13-15, 17-18, and 23-26 will be pending. Claim 8 has been cancelled. Claim 14 is withdrawn as being directed to a non-elected invention. Claims 1-4 and 13 are currently amended. Claims 23-26 are newly added. No new matter is added and support for the amendments is found throughout the specification and in the original claims.

### Claim rejections 35 U.S.C. §103(a)

In the Office Action of June 2, 2006, the Examiner rejected Claims 1, 8 and 13 under 35 U.S.C. §103(a) as unpatentable over Hsieh *et al.* (U.S. Patent Application Publication No. 2003/0022248 hereinafter "Hsieh"). Applicants respectfully submit that the amendments to the claims overcome the rejection.

Claim 1 has been amended to specify that the ligand is an antibody and the antibody lacks immunoreactivity with animal muscle tissue. Support for this amendment is found on page 11, lines 14-15 and page 28, lines 7-9. Claim 8 has been cancelled without prejudice.

Hsieh disclose the use of antibodies to skeletal Troponin I, a thermostable muscle protein, for the detection of species-specific meats. Therefore, Hsieh teaches that Troponin I is reactive with animal muscle tissues (paragraph 28). Hsieh fails to teach or suggest the use of antibodies to detect rendered animal byproducts in animal feed samples wherein the antibodies lack immunoreactivity to animal muscle tissue as set forth in the amended claims.

The Examiner rejected Claims 2 and 17 under 35 U.S.C. §103(a) as unpatentable over Hsieh in view of Voller (THE ENZYME LINKED IMMUNOSORBENT ASSAY, Diagnostic

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Horizons, Vol. 2, No. 1, 1978). Applicants respectfully submit that the amendments to the claims overcome the rejection.

Claim 2 depends from amended Claim 1 and contains all the limitations thereof. In addition, Claim 2 specifies that the antibody has an attached detectable label and a second antibody is bound to at least one location on a solid phase.

As mentioned above, Hsieh fails to teach or suggest a method utilizing antibodies able to detect rendered animal byproducts in animal feed samples while also lacking immunoreactivity to animal muscle tissue. Voller discloses an ELISA assay wherein an antibody detects the bound analyte. The deficiencies of Hsieh are not satisfied by the teachings of Voller because Voller also fails to teach or suggest the use of antibodies to detect rendered animal byproducts in animal feed samples in the absence of immunoreactivity to animal muscle tissue.

The Examiner rejected Claim 3 under 35 U.S.C. §103(a) as unpatentable over Hsieh in view of Schuurs *et al.* (U.S. Patent No. 3,654,090, hereinafter Schuurs) and further in view of Deger *et al.* (U.S. Patent No. 5,437,981, hereinafter Deger). Applicants respectfully submit that the amendments to the claims overcome the rejection.

Claim 3 depends from amended Claim 1 and contains all the limitations thereof. Claim 3 further specifies that the sample is combined with both the antibody (having a detectable label) and an analyte analog that is bound to the solid phase, and that the antibody has a binding affinity for the analyte analog.

As mentioned above, Hsieh fails to teach or suggest a method utilizing antibodies able to detect rendered animal byproducts in animal feed samples while also lacking immunoreactivity to animal muscle tissue.

Schuurs discloses a test system composed of an antigen, labeled antibody and insolubilized antigen, wherein the amount of soluble antigen can be measured from the distribution of labeled antibody over the liquid and solid phases. The deficiencies of Hsieh are not satisfied by the teachings of Schuurs because Schuurs also fails to teach or suggest

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the use of antibodies to detect rendered animal byproducts in animal feed samples in the absence of immunoreactivity to animal muscle tissue.

Deger discloses a competitive immunoassay utilizing an immobilized analogue of the analyte of interest. The amount of analyte in the sample is determined by the distribution of a labeled antibody between the liquid and solid phases. The deficiencies of Hsieh and Schuurs are not satisfied by the teaching of Deger because Deger also fails to teach or suggest a method utilizing antibodies for the detection of rendered animal byproducts in animal feed samples while lacking immunoreactivity to animal muscle tissue.

The Examiner rejected Claim 4 under 35 U.S.C. §103(a) as unpatentable over Hsieh in view of Jacobs *et al.* (U.S. Patent No. 5,571,682, hereinafter Jacobs) and further in view of Guan *et al.* (U.S. Patent No. 6,617,116, hereinafter Guan). Applicants respectfully submit that the amendments to the claims overcome the rejection.

Claim 4 depends from amended Claim 1 and contains all the limitations thereof. In addition, Claim 4 specifies that the sample is combined with both the antibody and a detectable analyte analog, and that the antibody is bound to a solid phase and has binding affinity for the detectable analyte analog.

As mentioned above, Hsieh fails to teach or suggest the use of antibodies to detect rendered animal byproducts in animal feed samples without immunoreactivity to animal muscle tissue.

Jacobs discloses a competitive immunoassay wherein the analyte of interest competes with a labeled analyte analog for binding to an immobilized antibody. The deficiencies of Hsieh are not satisfied by the teachings of Jacobs because Jacobs also fails to teach or suggest a method utilizing antibodies able to detect rendered animal byproducts in animal feed samples in the absence of immunoreactivity to animal muscle tissue.

Guan discloses a competitive immunoassay wherein an analyte of interest competes with a labeled analog analyte for binding to an immobilized binding partner. The deficiencies of Hsieh and Jacobs are not satisfied by Guan because Guan also fails to teach or suggest the

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use of antibodies lacking immunoreactivity to animal muscle tissue for detecting rendered animal byproducts in animal feed samples.

The Examiner rejected Claims 5-6 under 35 U.S.C. §103(a) as unpatentable over Hsieh in view of Ansfield (U.S. Patent No. 5,910,446). Applicants respectfully submit that the amendments to the claims overcome the rejection.

Claims 5 and 6 depend from amended Claim 1 and contain all the limitations thereof. Claim 5 further specifies that the amounts of bound complex can be determined. Claim 6 specifies that the analyte is a specific component, namely meat and bone meal, a commodity used as an ingredient in animal feed.

As mentioned above, Hsieh fails to teach or suggest a method utilizing antibodies able to detect rendered animal byproducts in animal feed samples while also lacking immunoreactivity to animal muscle tissue.

Ansfield provides a preparative method for concentrating heat stable proteins in order to increase the sensitivity of tests such as immunoassays that incorporate this method as a necessary preliminary step. The deficiencies of Hsieh are not satisfied by the teachings of Ansfield because Ansfield also fails to teach or suggest the use of antibodies lacking immunoreactivity to animal muscle tissue.

The Examiner rejected Claims 7 and 10 under 35 U.S.C. §103(a) as unpatentable over Hsieh in view of Thorn *et al.* (U.S. Patent Application Publication No. 2003/0083255, hereinafter Thorn). Applicants respectfully submit that the amendments to the claims overcome the rejection.

Claims 7 and 10 depend from amended Claim 1 and contain all the limitations thereof. Claim 7 further specifies that the analyte is a component of rendered connective tissue or bone. Claim 10 specifies that the analyte is a component of the extracellular matrix of bone or cartilage.

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As mentioned above, Hsieh fails to teach or suggest a method utilizing antibodies able to detect rendered animal byproducts in animal feed while also lacking immunoreactivity to animal muscle tissue.

Thorn discloses that Troponin I is a component of connective tissue. However, Hsieh teaches that Troponin I is a component of muscle tissue. Based on these references, while antibodies specific for Troponin I may be reactive with a component of connective tissue, such antibodies fail to lack immunoreactivity to animal muscle tissue as currently claimed. Therefore, the deficiencies of Hsieh are not satisfied by the teachings of Thorn because Thorn also fails to teach or suggest the use of antibodies that detect rendered animal byproducts in animal feed samples but lack immunoreactivity to animal muscle tissue.

The Examiner rejected Claim 11 under 35 U.S.C. §103(a) as unpatentable over Hsieh in view of Radziejewski *et al.* (U.S. Patent No. 6,022,694, hereinafter Radziejewski). Applicants respectfully submit that the amendments to the claims overcome the rejection.

Claim 1 has been amended to specify that the ligand is an **antibody**. Claim 11 depends from amended Claim 1 and contains all the limitations thereof. In addition, Claim 11 specifies that the analyte is chondroitin sulfate, aggrecan, osteocalcin, hyaluronic acid, or Type II collagen.

As mentioned above, Hsieh fails to teach or suggest a method utilizing antibodies able to detect rendered animal byproducts in animal feed samples while lacking immunoreactivity to animal muscle tissue.

Radziejewski discloses assays for detecting Type II collagen in a sample using the collagen binding domain of receptors DDR-1 and DDR-2. These receptors are not antibodies as set forth in the amended claims.

Therefore, the deficiencies of Hsieh are not satisfied by the teaching of Radziejewski, because Radziejewski also fails to teach or suggest a method utilizing **antibodies** able to detect rendered animal byproducts in animal feed samples in the absence of immunoreactivity to animal muscle tissue.

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In the Office Action of June 2, 2006, the Examiner rejected Claims 15 and 18 under 35 U.S.C. §103(a) as unpatentable over Hsieh in view of Foster *et al.* (U.S. Patent No. 4,444,879, hereinafter Foster). Applicants respectfully submit that the amendments to the claims overcome the rejection.

Claim 15 specifies a kit for performing the method of Claim 1. Claim 18 specifies that the amount of rendered animal byproduct detected is about 0.005% to about 0.01% by weight.

As mentioned above, Hsieh fails to teach or suggest a method utilizing antibodies able to detect rendered animal byproducts in animal feed samples while lacking immunoreactivity to animal muscle tissue. Foster discloses a solid-phase support for immobilizing reactants of an immunoreaction and methods for manufacture and use of the support for the invention in an immunoassay for proteins. The deficiencies of Hsieh are not satisfied by the teachings of Foster because Foster also fails to teach or suggest the use of antibodies lacking immunoreactivity to animal muscle tissue.

Therefore, for at least the foregoing reasons, applicants respectfully submit they have overcome the rejection under 35 U.S.C. §103(a) and request withdrawal thereof.

#### New Claims

Claims 23-26 are newly added. Support for the new claims can be found on page 10, lines 20-25.

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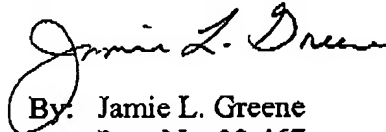
### CONCLUSION

Applicants respectfully submit that this is a complete response to the non-final Office Action dated June 2, 2006, and that the pending claims are definite, novel and non-obvious. Accordingly, applicants respectfully request allowance of these claims.

No additional fees are believed due, however, the Commissioner is hereby authorized to charge any deficiencies that may be required or credit any overpayment to Deposit Account Number 11-0855.

Early and favorable consideration is earnestly solicited. If the Examiner believes there are other issues that can be resolved by telephone interview, or that there are any informalities remaining in the application that may be corrected by Examiner's Amendment, a telephone call to the undersigned attorney at (404) 815-6500 is respectfully solicited.

Respectfully submitted,



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